

Prevention of preterm birth

Submission date 09/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/10/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

About 11% of all babies born worldwide are preterm (premature), meaning that they are born more than three weeks before their due date. The earlier babies are born, the more likely they are to die or develop long-term complications of brain, lung and gut development, particularly those born before 32 weeks. Prematurity is a huge emotional burden for families and communities, and a financial burden costing the public sector an extra £2.95 billion annually. Two-thirds of preterm births (PTB) happen spontaneously, the reason for which is unclear. Women who have previously had a PTB, have had important tissue removed from their cervix (neck of womb), or have a short cervix are more likely to give birth prematurely than the general population. There are currently three main treatments available which aim to help prolong pregnancy, preventing PTB: an arabin pessary, a cervical cerclage, or a vaginal progesterone pessary. It is currently not known which technique is the most effective. The aim of this study is to compare these treatments in a small study in order to find out whether it would be possible to later conduct a large-scale study.

Who can participate?

Women aged 18 and over who are between 16 and 24 weeks pregnant with a single baby, who are at risk of having a pre-term birth.

What does the study involve?

Participants are randomly allocated to receive one of three treatments: an arabin pessary (a silicone cup inserted vaginally to support the pregnancy), a cervical cerclage (a stitch placed surgically into the cervix), or a vaginal progesterone pessary (a vaginal tablet containing the hormone progesterone that is put in place by the patient every night). Patient and staff acceptability is measured 1-2 months after the end of the study, and the feasibility of recruiting participants for a large-scale study is assessed at 12 months after recruitment, along with an economic analysis.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
October 2015 to August 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Christine Cornforth (scientific)
2. Mrs Ediri O'Brien (public)

Contact information

Type(s)
Scientific

Contact name
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Public

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Additional identifiers

EudraCT/CTIS number
2014-003112-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

18675

Study information

Scientific Title

Three-arm randomised trial of cervical cerclage, arabin pessary and vaginal progesterone to prevent spontaneous preterm birth in asymptomatic women at high-risk of preterm birth: A feasibility study

Study objectives

The aim of this study is to explore the feasibility of recruiting participants for a large-scale clinical trial looking at different treatments designed to prevent preterm labour.

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/NW/1392

Study design

Three-arm multi-centre randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Reproductive Health; Subtopic: Reproductive Health & Childbirth (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions

Participants are randomly allocated to receive one of three treatments:

1. Arabin pessary: silicone cerclage pessary device sited around cervix in clinic
2. Cervical cerclage: Macdonald technique to site suture, surgically in cervical tissue. Performed in theatre under aseptic technique

3. Vaginal progesterone: single administration vaginal micronised progesterone pessary (Uterogestan) 200mg nocte pv, prescription given in clinic and collected from pharmacy

Intervention Type

Mixed

Primary outcome measure

Feasibility is measured at 12 months post recruitment, with follow up until final mother and baby discharge or 6 weeks postnatal.

Secondary outcome measures

1. Economic analysis is completed at 12 months post recruitment
2. Patient and staff acceptability is measured 1-2 months post study completion

Overall study start date

06/10/2015

Completion date

31/08/2017

Eligibility

Key inclusion criteria

1. Aged 18 years or older
 2. Singleton pregnancy
 3. Between 16+0 – 24+6 weeks in current pregnancy
 4. History of previous spontaneous preterm birth (sPTB) or premature rupture of membranes (PPROM) between 16-33+6
- AND
5. Cervical length at least <3rd centile for gestational age
- OR
6. History of significant cervical surgery defined as two large loop excision of the transformation zone (LLETZ) procedures or a single knife cone biopsy (KCB) where a clinical decision is made to treat the short cervix
 7. Clinical equipoise as to what is the best treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Planned Sample Size: 39; UK Sample Size: 39

Key exclusion criteria

1. Known or suspected structural or chromosomal fetal abnormality
2. Inability to give informed consent
3. Treatment with history indicated cerclage
4. Treatment with vaginal progesterone within two weeks of randomisation
5. All contraindications to use of progesterone (see protocol 6.2)

Date of first enrolment

06/10/2015

Date of final enrolment

31/08/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Cancer Research UK Liverpool Cancer Trials Unit

University of Liverpool

1st floor Block C

Waterhouse Building

3 Brownlow Street

Liverpool

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L69 3GL

Sponsor information**Organisation**

University of Liverpool (UK)

Sponsor details

Department of Pharmacology and Therapeutics

Liverpool

England

United Kingdom

L69 3BX

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

31/08/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No